

REMARKS

Claims 1, 5-13, 16-18 and 38-50 remain in the application for further prosecution.

Claims 1 and 38 have been amended to distinguish the newly cited response.

Rejection Under 35 U.S.C. 102

Claims 1, 5-8, 11, 12, 38-42, 45 and 46 have been rejected under 35 U.S.C. 102 (b) as anticipated by Shartle, et al. ("Shartle"), U.S. 5,230,866. Shartle is a newly cited reference. It teaches improved "stop-flow junctions", which are defined by Shartle as places where liquid flowing by capillary action stops until some outside force is applied. In some aspects, the capillary stops of the present applicants could be considered to be stop-flow junctions. However, the improvements disclosed by Shartle are unique. For example, Shartle proposed blocking an external vent to build air pressure that assists in stopping liquid flowing in a capillary at a stop-flow junction. He also proposed using a nozzle designed to assist stopping liquid flow at the entrance to a chamber and using a rupture junction to relieve pressure creating by closing of valves in his device.

The Examiner has cited passages in Shartle to support his rejection for anticipation. These will be considered in more detail below. However, it should be understood that the Shartle disclosure is principally directed to a device which is referred to as a "diluter". They combine a liquid sample with diluents and the improved "stop-flow junctions" are employed in the movement of the sample and the diluents. Further processing involving the use of reagents is described generally in column 21 and exemplified in Fig. 6 and columns 28/29. Diluents are used to move the sample into reaction chambers.

Amended Claim 1	Shartle
1. A device for dispersing and analyzing a uniform volume of a liquid sample comprising:	<ul style="list-style-type: none">• Shartle is principally concerned with improved "stop-flow junctions", but he does describe an example in which a uniform volume of a sample is analyzed.
(a) a sample well for receiving a portion of said liquid sample;	<ul style="list-style-type: none">• Shartle shows a sample inlet (110) but <u>not</u> a sample well. His flow directing chamber (130) is found only in Fig.1 and it also receives diluent from chamber 175. The cited description at column 14, line 64 to column 15, line 15 does not describe a sample well as

(b) a hydrophilic capillary passageway communicating with said sample well of (a) for receiving said liquid from said sample well by capillary action, said passageway including a segment defining said uniform volume of said liquid sample,

said uniform volume being disposed between two vents from said passageway to the atmosphere,

said segment in liquid communication with a transfer hydrophilic capillary passageway for transferring said uniform volume of said liquid sample through an entrance to said segment between said vents to a first reagent well; and

(c) a hydrophilic capillary stop disposed within said transfer hydrophilic capillary passageway for preventing transfer of said uniform sample volume until the resistance of said stop is overcome by a means for applying force other than centrifugal force.

defined by the present invention.

- Shartle does provide a capillary passageway (120) from his sample inlet (110) which enters a "measuring chamber" (140), which corresponds to the capillary segment of the invention.

- In his figures, Shartle does not appear to define a uniform volume between two vents to the atmosphere. The discussion at column 18, lines 25-57 is merely general in nature.

- Shartle's device does not provide a transfer capillary from his measuring chamber (140). In Fig. 1 the measuring chamber 140 terminates at mixing chamber 150 and diluent from 175 is used to push the sample from 140 into 150. In Fig. 5 and 6 the measuring chamber 140 also terminates at 150 and 175 so that no transfer capillary is present. Furthermore, the transfer passageway is now defined as connecting the measuring segment between the vents to atmosphere, which is not used in Shartle's device. The passage at column 17, line 62 to column 18, line 2 describes a passageway through which diluent flows into the measuring chamber 140 to expel the sample into the mixing chamber.

- Shartle has no transfer passageway and thus has no capillary stop in the passageway. In the present invention, the stop is overcome in order to empty the segment between the vents to atmosphere. In Shartle the sample is displaced by diluent and the measuring chamber is not emptied from between vents to atmosphere.

The above comparison applies also to independent claim 38.

The Examiner contends that the second and third reagent wells of claims 4, 5, 39, and 40 are inherently present in Shartle and that those claims are also anticipated. This assertion is not supported by the general discussion cited at column 21, lines 1-67.

The Applicant's submit that in view of the differences discussed above, that Shartle does not anticipate the amended claims.

Rejection under 35 U.S.C. 103

Claims 1, 5-13, 16-18, and 38-50 have been rejected under 35 U.S.C. 103(a) as unpatentable (i.e. obvious) over McNeely, et al. (US 6,296,020)("McNeely '020") in view of Kellogg, et al. (US 6,063,589("Kellogg")) and further in view of McNeely, et al. (US 6,615,856)("McNeely '856").

The Examiner has repeated his previous rejection based on McNeely '020 and Kellogg and added McNeely '856. As discussed in detail in the previous amendment, McNeely '020 does not show a sample well, which supplies a reagent well with a sample volume defined by a segment of a hydrophilic capillary which is disposed between two vents.

In general, McNeely '020 shows devices for splitting liquid into multiple wells or combining several liquids in a single well, using passive stops. McNeely '020 evidently preferred using hydrophobic passageways with aqueous liquids, combined with hydrophilic stops (see column 3, lines 59-62, the discussion above and the claims). McNeely '020 does not show a sample well connected to a capillary passageway that contains a segment defining a sample volume, which is transferred to a reagent well. The Examiner's citations of the McNeely '020 patent were discussed in a table in the previous amendment.

From that table, it should have been clear that McNeely '020 fails to support the Examiner's position. McNeely '020 does not just lack the use of a hydrophilic capillary to transfer liquid, but he fails to describe a device that separates a defined volume of a larger sample and transfers that defined volume to a reagent well. Furthermore, McNeely '020 appears to teach that use of a second liquid or a gas to force a first liquid past capillary stops. Also, he appears to use hydrophobic passageways with water-based liquids, implying that capillary forces are not used to transport liquid.

Kellogg describes devices in which centrifugal force is used to transfer liquids after a sample liquid fills the group of capillaries used to define the sample volume to be tested. The sample volume is not defined by a portion of a hydrophilic capillary positioned between two vents, but instead the entire capillary is between a chamber at one end and the sample well at the other end (the excess sample having been sent using centrifugal force to the over flow well).

McNeely '020 does not show essential elements of the Applicants' claimed invention and forces liquid through with other liquids or gas. Kellogg relies on increasing centrifugal force to transfer liquid through his devices. There is no reason why one skilled in the art would consider a combination of McNeely '020 and Kellogg. The Kellogg devices are designed to move liquid and expel air with increasing centrifugal force and therefore are not combinable with the McNeely '020 devices. Kellogg would have to redesign his device to be operated by a driving liquid or gas as done by McNeely. Alternatively, McNeely '020 would have to be redesigned to operate by centrifugal force. Consequently, different devices would be provided, but not those of McNeely '020 or of Kellogg, since they have different objectives.

The reasons for adding McNeely '856 are not understood. It may be that the Examiner has misread this reference. The McNeely '856 patent teaches a method of controlling fluid flow in a microfluidic device in which external valves and pumps are employed (see Abstract). Since capillary forces are not used by McNeely's devices, the flow of liquids is controlled by opening and closing vents. As he shows in Fig. 1 A-C, liquid flow is stopped beyond an air vent since the external force applied is not able to compress the air trapped in the dead-ended passageway. The general approach is discussed in the section entitled "Flow Barriers" (column 4, line 33 et seq.). As McNeely observes "if capillary forces cannot be relied upon, ...then alternative methods of fluid control are needed" (column 4, lines 37-40). "An alternative to capillary stop junctions and the like are pneumatic pressure barriers" (column 4, lines 45-46). It appears then, that McNeely '856 is not pertinent to the Applicant's invention.

Consequently, the Examiner is asked to reconsider his rejection and allow the claims as amended. If further amendment is believed necessary, the Examiner is invited to contact the Applicants' attorney at the telephone number provided below.

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Date

Respectfully submitted,

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